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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,191	11/24/2003	Richard Gibbons	PA1700 US	6737
28390 7590 01/23/2009 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403				
EXAMINER HOUSTON, ELIZABETH				
ART UNIT		PAPER NUMBER		
3731				
NOTIFICATION DATE		DELIVERY MODE		
01/23/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

### Office Action Summary

**Application No.**

10/722,191

**Applicant(s)**

GRIBBONS ET AL.

**Examiner**

ELIZABETH HOUSTON

**Art Unit**

3731

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,905,477 in view of Cude (US 5527299) and Anthony (US 4,101,123). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the patent claim all the limitations in the instant claims except for the guide member having an outer member being selectively rotatable around the inner member. However, Cude discloses that it is well known in the art for a catheter shaft to rotate as it follows a tortuous path through the blood vessel. To avoid torque from building up in the catheter tube it would be necessary to allow the catheter and thus the handle to rotate as it is

guided through the tortuous vasculature. However, this could be awkward for the user to constantly have to change hand positions throughout the delivery process. It would therefore have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an outer handle element that rotates freely relative to the inner element as taught by Anthony in order to allow the user to maintain contact with the catheter handle while the catheter is being guided through the tortuous vasculature.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 1-5, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (USPN 5,334,187) in view of Cude (US 5527299) and Anthony (US 4,101,123).
3. Fischell discloses a catheter and guide wire exchange system comprising:
  - a. An elongate flexible catheter shaft (20) having proximal and distal shafts and first (23) and second (22) lumens extending there through, the first lumen being open at the shaft distal end ( 55) and being sized and shaped to slidably receive a guide wire (12);
  - b. A longitudinal guide way (25) formed in the proximal shaft to enable transverse access to the first lumen through the proximal shaft, the guide way

extending along a major portion of the length of the proximal shaft from a location adjacent a proximal end of the proximal shaft to a distal terminal end proximal of a distal end of the proximal shaft, thereby defining an uncut distal segment of the proximal shaft (23);

c. A balloon mounted about a distal segment of the distal shaft (54), the balloon being in fluid communication with the second lumen;

d. And a guide member (30) slidably mounted on the proximal shaft and having an inner member (41). The inner member has a catheter passageway (38) extending there through for slidably receiving the catheter shaft (21) and a guidewire passageway (43) for slidably receiving a guidewire (12) (see Fig. 5) for merging the guide wire and the catheter by guiding the guide wire transversely through the guide way and into the first lumen and for separating the guide wire and catheter by guiding the guide wire transversely out of the first lumen through said guide way (C4: L35-C6: L20), the guide member including a keel (47) for tracking the guide way.

e. The keel (47) has a passageway for receiving the guidewire and the inner member has a guidewire passageway in communication with the keel guidewire passageway. The guidewire passageway of the inner member is in communication with the keel guide wire passageway (Figs. 4c and 6).

4. Fischell does not disclose an outer member on the guide member that is selectively rotatable relative to and around the inner member.

5. However, Cude discloses that it is well known in the art for a catheter shaft to rotate as it follows a tortuous path through the blood vessel. To avoid torque from building up in the catheter tube it would be necessary to allow the catheter and thus the handle to rotate as it is guided through the tortuous vasculature. However, this could be awkward for the user to constantly have to change hand positions throughout the delivery process. It would therefore have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an outer handle element that rotates freely relative to the inner element as taught by Anthony in order to allow the user to maintain contact with the catheter handle while the catheter is being guided through the tortuous vasculature.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Arenas as applied to claim 1 above, and further in view of Farivar (US 5,250,036).

7. Fischell modified by Cude and Anthony discloses the invention substantially as claimed except for the outer member having a textured surface with circumferential bosses. However Farivar discloses a catheter handle having circumferential bosses (63) in order to provide a desired contour for efficient grasping and manipulation of the device (C6: L62-68). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a textured surface into the handle in order to improve the grasping capabilities.

***Response to Arguments***

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ELIZABETH HOUSTON** whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./  
Examiner, Art Unit 3731

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731